IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: COLOPLAST CORP.
PELVIC SUPPORT SYSTEMS PRODUCTS LIABILITY LITIGATION — MDL NO. 2387

THIS DOCUMENT RELATES TO:

Mavis Hicks and James Hicks v. Coloplast Corp. — *Civil Action No. 2:13-cv-14547*

MEMORANDUM OPINION & ORDER

Pending before the court is Coloplast Corp.'s Motion to Dismiss on the Pleadings [ECF No. 16]. The plaintiffs responded [ECF No. 21] and Coloplast Corp. replied [ECF No. 22] making the Motion ripe for adjudication. For the reasons set forth below, the Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 500 of which are in the Coloplast Corp. ("Coloplast") MDL, MDL 2387.

On November 30, 2011, Ms. Hicks was surgically implanted with Coloplast's Suspend-Tutoplast Processed Fascia Lata ("Fascia Lata"), a device manufactured by

Coloplast to treat SUI and to reconstruct the pelvic floor.[1] Am. Short Form Compl. ¶¶ 9–10 [ECF No. 15]. Ms. Hicks' surgery occurred at Ms. Baptist Medical Center in Jackson, Mississippi. *Id.* ¶ 11. Ms. Hicks claims that as a result of implantation of the Fascia Lata, she has experienced multiple complications. She adopts the following counts as alleged in the First Amended Master Long Form Complaint and Jury Demand ("Master Complaint"): I – negligence, II – strict liability design defect, III – strict liability manufacturing defect, IV – strict liability failure to warn, V – strict liability defective product, VI – breach of express warranty, VII – breach of implied warranty, XIV – gross negligence, XVI – loss of consortium, and XVII – punitive damages. *Id.* ¶ 13.

According to the Master Complaint, Coloplast "designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products," one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23 [ECF No. 49, MDL 2387]. Coloplast admits in its Joint Master Long Form Answer and Affirmative Defenses to Plaintiffs' First Amended Master Long Form Complaint and Jury Demand ("Master Answer") that it "generally packaged, labeled, marketed, sold[,] and distributed" such pelvic mesh devices. Master Answer ¶ 22 [ECF No. 62, MDL 2387]. The Fascia Lata device is "dehydrated, . . . processed fascia lata from donated human tissue." *See* Def.'s Mot. Dismiss on the Pleadings Ex. B, at 1 [ECF No. 16-2] ("Package Insert"). The Fascia Lata is preserved such that it

[1] The plaintiffs also allege in her short form complaint that she was implanted with "Coloplast Mesh Product(s), specific product name(s) unknown at present." Am. Short Form Compl. ¶ 8. This Order only addresses the plaintiff's claims insofar as they pertain to the Suspend-Tutoplast Processed Fascia Lata.

"retains the three-dimensional collagen structure responsible for the unidirectional, mechanical properties of the original fascia lata tissue." *Id.*

II. Legal Standard

"[T]he Rule 12(c) judgment on the pleadings procedure primarily is addressed to . . . dispos[e] of cases on the basis of the underlying substantive merits of the parties' claims and defenses as they are revealed in the formal pleadings." 5C Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1367 (3d ed. 2004). A motion under 12(c) is useful when only questions of law remain. *Id.*

> [A] Rule 12(c) motion is designed to provide a means of disposing of cases when the material facts are not in dispute . . . and a judgment on the merits can be achieved by focusing on the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense . . . .

Id. Rule 12(h)(2) provides that the defense of failure to state a claim upon which relief can be granted may be raised in a motion for judgment on the pleadings. Fed. R. Civ. P. 12(h)(2). If this is asserted in a Rule 12(c) motion, the district court will apply the same standards for granting the appropriate relief or denying the motion as it would have employed had the motion been brought prior to the defendant's answer under 12(b)(6). Wright & Miller, *supra*, § 1367; *see Exec. Risk Indem., Inc. v. Charleston Area Med. Ctr., Inc.*, 681 F. Supp. 2d 694, 706 n.17 (S.D. W. Va. 2009) ("[T]he standards under Federal Rule of Civil Procedure 12(c) for a motion for judgment on the pleadings are identical to those applicable to a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss.").

A motion to dismiss filed under Rule 12(b)(6) tests the legal sufficiency of a complaint or pleading. *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). A pleading submitted to federal court, whether arising under state law or federal law,[2] must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Andresen v. Diorio*, 349 F.3d 8, 17 (1st Cir. 2003). This standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). To achieve facial plausibility, the plaintiffs must plead facts allowing the court to draw the reasonable inference that the defendant is liable, moving the claim beyond the realm of mere possibility. *Id.* Mere "labels and conclusions" or "formulaic recitation[s] of the elements of a cause of action" are insufficient. *Twombly*, 550 U.S. at 555.

III. Discussion

The plaintiffs assert that Coloplast's Rule 12(c) Motion to Dismiss on the Pleadings is truly a Rule 56 Summary Judgment Motion because Coloplast has

[2] The plaintiffs contend in their Response that they have satisfied Mississippi's state court pleading standards. Resp. at 2 [ECF No. 21]. However, Mississippi procedural law is immaterial. As this case was originally filed in the U.S. District Court for the Northern District of Mississippi, the Federal Rules of Civil Procedure govern this action. *See* Fed. R. Civ. P. 1. (explaining that the Federal Rules of Civil Procedure "govern the procedure in all civil actions and proceedings in the United States district courts"); *see Morel v. DaimlerChrysler AG*, 565 F.3d 20, 24 (1st Cir. 2009) (noting that "a federal rule controls notwithstanding that an inconsistent state rule would, if applied, have resulted in a different outcome.").

attached exhibits for the court's consideration. However, when deciding a 12(c) motion, the court may consider "the content of the competing pleadings, exhibits thereto, matters incorporated by reference in the pleadings, [and] whatever is central or integral to the claim for relief or defense." Wright & Miller, *supra*, § 1367. Of Coloplast's attached documents, the court will consider the package insert marked as Exhibit B to Coloplast's Motion because it is integral to the claim for relief and defense. *See* Package Insert. The package insert offers a product description and a warranty statement which are pertinent to the claims at hand—specifically the breach of warranty claims. *See id.* at 1; Am. Short Form Compl. ¶ 13. Further, Coloplast attached the Amended Short Form Complaint as Exhibit A to its Motion. *See* Def.'s Mot. Dismiss on the Pleadings Ex. A [ECF No. 16-1]. This *is* a pleading and must be considered by the court, and accordingly has no transformative power. Thus, Coloplast's Motion is not a Rule 56 Summary Judgment Motion.

Next, this court applies the substantive tort law of the state where the plaintiffs' implantation occurred—in this case, Mississippi. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-cv-760, 2016 WL 3067752, at *2 (S.D. W. Va. May 31, 2016); Am. Short Form Compl. ¶ 11. The claims are addressed below.

a. Strict Liability and Breach of Warranty (Counts II–VII)

Coloplast argues that it is immune from the plaintiffs' strict liability and warranty claims alleged in Counts II-VII by virtue of Mississippi's blood and human tissue shield statute which states in relevant part:

> The procurement, processing, storage, distribution and/or use of whole blood, plasma, blood products and blood derivatives, human tissue,

> organs or bones for the purpose of injecting, transfusing, transplanting or transferring the same or any of them into the human body for all purposes whatsoever constitutes the rendering of a service by every person participating therein, whether or not any remuneration is paid therefor, and does not constitute a sale.

Miss. Code. Ann. § 41-41-1. Where a statute such as this one clearly defines the distribution of "human tissue" to be a service, there can be no sale of a product subject to products liability actions.[3] *See Palermo v. LifeLink Found., Inc.*, 152 So. 3d 1177, 1181 (Miss. Ct. App. 2014) (explaining that "human tissue provided to others in medical procedures is not a 'product' subject to products-liability law, and the distribution of human tissue, including reasonable payments for related services, does not constitute a 'sale' for purposes of strict liability."). Additionally, Mississippi's highest court analyzed the legislative intent behind § 41-41-1 and came to the same conclusion. *See Palermo v. LifeLink Found., Inc.*, 152 So. 3d 1099, 1106 (Miss. 2014) ("Section 41–41–1 indicates that the [Mississippi] Legislature intended to exempt 'every person participating' in the 'procurement, processing, storage, distribution, and/or use' of . . . 'human tissue . . . for . . . transplanting or transferring the same . . . into the human body' from liability under the theory of strict products liability.").

It follows that the plaintiffs' warranty claims also fail for this reason. As the Fifth Circuit has explained:

> It is axiomatic, of course, that breach of express warranty is not available as a cause of action without a sale, because the essence of warranty is a consensual agreement— express or implied— arising from

[3] The term "products liability" is used in reference to both strict liability and breach of warranty claims. *See* 63 Am. Jur. 2d *Products Liability* § 625 (2010) ("An action for products liability may be brought under several theories, including . . . strict liability, and warranty.").

> contract. Without a sale under contract, there is no consensual nexus between the parties and thus no warranties may attach.

Heirs of Fruge v. Blood Servs., 506 F.2d 841, 846 (5th Cir. 1975) (citation omitted) (interpreting a statute defining tissue as a medical service and expressly exempting contracts for the sale of human tissue from breach of warranty claims); *see also Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226, 1227 & n.1 (D. Utah 2002) (recognizing that the analysis for breach of warranty claims is the same as strict liability).

The Restatement of Torts gives even more credence to the idea that human tissue is not a "product" and thus not subject to products liability claims. The Restatement (Third) of Torts elaborates on products liability law in the context of human tissue and states: "Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement." Restatement (Third) of Torts § 19(c) (Am. Law Inst. 1998). This update clarifies that human tissue, such as the allograft in this case, is not a "product" and is consistent with the nationwide policy against applying strict liability to the distribution of human tissue. *See id.* at § 19(a)–(c), cmt. c.

Where the statutory language varies modestly between jurisdictions, the public policy behind blood and human tissue shield statutes remains the same. On this matter, the California Court of Appeal stated:

> [L]egislatures have determined that the production and use of human blood and its derivatives for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally.

Cryolife, Inc. v. Super. Ct., 2 Cal. Rptr. 3d 396, 405 (Cal. Ct. App. 2003) (emphasis omitted) (quoting *Hyland Therapeutics, Inc. v. Super. Ct.*, 220 Cal. Rptr. 590, 594 (Cal. Ct. App. 1985)). Moreover, there is "a nationwide antipathy over applying products-liability or strict-liability concepts to body parts such as blood and tissue." *Palermo*, 152 So. 3d at 1181. Indeed, "no court has ever applied strict liability to the distribution of human tissue." *Condos*, 208 F. Supp. 2d at 1229; *see Palermo*, 152 So. 3d at 1181.

According to the Master Complaint, Coloplast "designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products," one of which was an allograft, the Fascia Lata. First Am. Master Compl. ¶¶ 22–23. Coloplast admits in its Master Answer that it "generally packaged, labeled, marketed, sold[,] and distributed" such pelvic mesh devices. Master Answer ¶ 22. Thus, it is not in dispute that Coloplast distributed the Fascia Lata allograft. Per its labeling, the allograft is "dehydrated, Tutoplast processed Fascia [L]ata from donated human tissue." Package Insert 1. The plaintiffs do not dispute this fact either. Because there is no dispute as to whether Coloplast distributed processed human tissue, the Fascia Lata, no discovery is needed to determine whether the statute applies, as the plaintiffs suggest.[4] Coloplast's actions are plainly covered by

[4] The court acknowledges that Coloplast's status as a commercial distributor does not change the applicability of the statute. Human tissue and blood shield statutes have been interpreted to apply to for-profit entities. *See, e.g.*, *Coffee v. Cutter Biological*, 809 F.2d 191, 193 (2d Cir. 1987) (interpreting Connecticut's human tissue and blood shield statute's use of "blood bank" to include commercial manufacturers and distributors); *Cryolife*, 2 Cal. Rptr. 3d at 404 ("When the Legislature enacted section 1635.2 in 1991 as part of a regulatory scheme for tissue banks, it had to know that tissue banks are paid for their activities in connection with providing human cadaver tissue for medical use. By expressly deeming such activities to constitute a service, the Legislature must have intended a tissue bank to be immune from strict liability, just like a pharmacy.").

the statute and must be considered a "service." Public policy, precedent, and the plain language of the statute all dictate that the plaintiffs' strict liability and breach of warranty claims must fail.

The plaintiffs further argue that discovery is needed to identify other conduct that may allow a claim for strict liability to go forward. It is well-settled law, however, that the scope of discovery may not exceed the boundaries of the complaint. *See Cuomo v. Clearing House Ass'n, LLC*, 557 U.S. 519, 531 (2009) ("Judges are trusted to prevent 'fishing expeditions' or an undirected rummaging through . . . records for evidence of some unknown wrongdoing.").

Therefore, Counts II–VII of the plaintiffs' Amended Short Form Complaint, which correspond with Counts II–VII in the Master Complaint, are **DISMISSED with prejudice**.

b. Remaining Claims (Counts I, XIV, XVI–XVII)

Given the plaintiffs' Steering Committee's impending motion to amend the Master Complaint contemplated in the plaintiffs' Response, the nature of a short form complaint, and for reasons appearing to the court, the Motion is **DENIED** at this time as to all other claims (Counts I, XIV, XVI–XVII).

IV. Conclusion

For the reasons stated above, it is **ORDERED** that Coloplast's Motion for Judgment on the Pleadings [ECF No. 16] is **GRANTED in part** and **DENIED in part**. The Motion is **GRANTED** with respect to Counts II–VII and is otherwise **DENIED** at this time. Counts II–VII are **DISMISSED with prejudice**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 22, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE